



DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO-P-2021-0053]

Grant of Interim Extension of the Term of U.S. Patent No. 6,406,699; ECI® (ELIAS Cancer Immunotherapy)

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting a one-year interim extension of the term of U.S. Patent No. 6,406,699 ('699 patent).

FOR FURTHER INFORMATION CONTACT: Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, at 571-272-7728 or raul.tamayo@uspto.gov.

SUPPLEMENTARY INFORMATION: 35 U.S.C. 156 generally provides that the term of a patent may be extended for a period of up to five years, if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review. 35 U.S.C. 156(d)(5) generally provides that the term of such a patent may be extended for no more than five interim periods of up to one year each, if the approval phase of the regulatory review period (RRP) is reasonably expected to extend beyond the expiration date of the patent.

On September 6, 2022, TVAX Biomedical I, LLC, the owner of record of the '699 patent, timely filed an application under 35 U.S.C. 156(d)(5) for a fourth interim extension of the term of the '699 patent. The '699 patent claims a method of using a veterinary biological product in the cancer immunotherapy treatment known by the tradename ECI® (ELIAS Cancer Immunotherapy). The application for interim patent term extension indicates that a RRP as described in 35 U.S.C. 156(g)(5)(B)(ii) began for ECI® (ELIAS Cancer Immunotherapy) and is

ongoing before the United States Department of Agriculture, Center for Veterinary Biologics, for permission to market and use the product commercially.

Review of the interim patent term extension application indicates that, except for permission to market or use the product commercially, the '699 patent would be eligible for an extension of the patent term under 35 U.S.C. 156. Because it is apparent that the RRP will continue beyond the thrice-extended expiration date of the '699 patent, i.e., October 5, 2022, a fourth interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A fourth interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 6,406,699 is granted for a period of one year from the thrice-extended expiration date of the '699 patent.

Robert Bahr,

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United States Patent and Trademark Office.*

[FR Doc. 2022-21118 Filed: 9/28/2022 8:45 am; Publication Date: 9/29/2022]